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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION O

RESIDUE CHEMISTRY

Series 171-4

Magnitude of the Residue: Processed Food/Feed Study

ADDENDUM 4 ON DATA REPORTING

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ADDENDUM 4 to Pesticide Assessment Guidelines, Subdivision O, Hazard Evaluation: Residue Chemistry (EPA-540/9-82-023 and NTIS Order Number PB83-153961), October, 1982

16. Abstract (Limit: 200 words)

The Data Reporting Guideline (DRG) for Magnitude of the Residue: Processed Food/Feed Study, Series 171-4, gives guidance to pesticide registrants on the format for their study report so that the Agency can review it efficiently. This guidance clarifies sections in the existing Pesticides Assessment Guidelines, Subdivision O, on data reporting. It provides an outline for the study report, describes the topics which should be addressed and provides guidance on the presentation of the results of the study. Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 requirements for the registration of pesticides.

The DRG for Series 171-4, Magnitude of the Residue: Processed Food/Feed Study is only one of a number of DRG's published by the National Technical Information Service as an addendum to Subdivision O of the Pesticide Assessment Guidelines.

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Subdivision O - Magnitude of the Residue: Processed Food/Feed Study

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PESTICIDE ASSESSMENT GUIDELINES

RESIDUE CHEMISTRY

Magnitude of the Residue: Processed Food/Feed Study 1/2/

Subdivision O, Series 171-4

DATA REPORTING

INTRODUCTION

A. Purpose

Residue chemistry data on the magnitude of the residue in processed food/feed are conditionally required by 40 CFR 158.125 to support the registration of any pesticide intended for use on a food or feed crop under the amended Federal Insecticide, Fungicide, and Rodenticide Act. Specifically, data on the identity and magnitude of the residue in processed food/feed are required whenever there is a possibility of residue levels in processed food/feed exceeding the level in the raw agricultural commodity [r.a.c.] from which it is processed, thereby requiring establishment of a food additive tolerance.

Residue chemistry data on processed food/feed are used by the Agency to estimate the exposure of the general population to pesticide residues in foods (including animal commodities) and for setting and enforcing food additive tolerances for pesticide residues in or on processed food/feed under provisions of Section 409 of the Federal Food, Drug, and Cosmetic Act. [Note: Raw agricultural foods and feeds are regulated under Section 408 of the Act.]

Data on the level of residue in food as consumed are conditionally required under 40 CFR 158.125 when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Such data are used by the Agency to obtain a more precise estimate of potential dietary exposure. 3/

Residue chemistry data on processed food/feed are also needed to support the adequacy of one or more methods for the enforcement of the food additive tolerance, and to support practical methods (e.g., washing, trimming/peeling, etc.) for removing residues on food prior to processing.

This particular Data Reporting Guideline document addresses processed food and feed commodities, and is intended to be an adjunct to the Data Reporting Guideline on Magnitude of the Residue: Crop Field Trials. 4/

B. Objective

A processed food/feed study should answer the following question: What is the maximum level of the "total toxic residue" that will

likely result in the various processed food/feed commodities resulting from standard (or simulated) commercial processing as compared with the residue level in the raw agricultural commodity from which these processed commodities were prepared [i.e., are concentration factors, if any, ascertainable, or is the processing adequate for estimation of residues in ready-to-eat food?].

The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.

An effort should be made to achieve harmonization with applicable International Residue Limits (Codex) residues in processed food/feed.

Processing studies must simulate commercial practices as closely as possible. Raw agricultural commodity (r.a.c.) samples used in processing studies must contain field-treated detectable residues, preferably at or near the proposed tolerance level, so that concentration factors for the various by-products can be determined. This may require field treatment at exaggerated application rates to obtain sufficient residue levels for processing studies. Processing studies utilizing spiked samples are not acceptable unless it can be demonstrated that the r.a.c. residue consists entirely of a surface residue.

This Data Reporting Guideline is designed to aid the petitioner/registrant in generating reports which are compatible with the Agency's review process. Data submitters are encouraged to submit complete reports which can be efficiently reviewed by the Agency. 5/ This guidance pertains to the substance of the data report. PR Notice 86-5, effective November 1, 1986 (available from the Registration Support and Emergency Response Branch, Office of Pesticide Programs, US EPA), pertains to the physical formatting of reports (which are referred to as "studies") and submittal packages. Some of the requirements in PR Notice 86-5 are mandatory.

RESPONSE TO PUBLIC COMMENTS

The purpose of this section is to acknowledge and address the concerns expressed in the letters of comment received by the Agency in response to the public notice in FEDERAL REGISTER Volume 51, No. 199, p. 36753, October 15, 1986.

This addendum to the Pesticide Assessment Guidelines (Subdivision O) is to be considered an all-encompassing document. EPA recognizes there are sections in the addendum which do not apply in all cases. Therefore, registrants should exercise scientific judgment in deciding which portions are germane to a specific data submission.

This Data Reporting Guideline is not intended to introduce new data

requirements or revisions into the Pesticide Assessment Guidelines (Subdivision O); nor is it intended for use by Agency data reviewers as a mere checklist. It is intended to clarify ambiguities in interpretation of those existing Guidelines, and to organize the submission of data to facilitate the review process.

For comments relating to Good Laboratory Practices (GLPs), the Agency has revised its requirement in this document in recognition that there is currently no regulatory GLP Guideline for chemistry data.

GUIDELINE

TITLE/COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data if relevant to the study report should precede the content of the study formatted below. These requirements are described in PR Notice 86-5.

TABLE OF CONTENTS

I. SUMMARY/INTRODUCTION

- Purpose
- Results [include Summary Tables of Processing Study Data; Method Recovery Data; and Storage Stability Validation Data (if any)];
- Discussion [including explanations for apparently aberrant or atypical values; need for food/feed additive tolerances; etc.]

II. MATERIALS

A. Test Substance

1. Identification of the pesticide formulated product used in the field trial from which the r.a.c. used in the processing study was derived, including the active ingredient therein;

2. Identification and amount of residue(s) in experimentally treated r.a.c. samples at the time of harvest (i.e., weathered) or of fortification (if applicable), and also at the time the processing study is initiated;

3. If fortified r.a.c. samples were used in the processing study, identify the nature and amount of the fortifying substance(s);

4. Other [any and all additional information the petitioner considers appropriate and relevant to provide a complete and thorough description and identification of the test substance(s) used in the processing study.]

B. Test Commodity

1. Identification of the r.a.c.(s) (crop/type/variety) and the specific crop part(s) used in the processing study;

2. Sample identification [source of sample(s); field trial identification number; control or weathered residue sample; coding and labeling information (should be the same as--or cross-referenced to--the sample coding/labeling assigned at harvest)];

3. Treatment histories [pesticide(s) used, rate(s), number of applications, PHIs, etc.] of the r.a.c. samples used in the processing study. [Note: r.a.c. samples with detectable residue levels, preferably at or near the proposed tolerance level, should be used in the processing study.];

4. The developmental stage(s), general condition [immature/mature, green/ripe, fresh/dry, etc.] and size(s) of the r.a.c. samples used in the processing study;

5. Other [any and all additional information the petitioner considers appropriate and relevant to provide a complete and thorough description of the r.a.c.(s) used in the processing study].

III. METHODS

A. Experimental Design [e.g., number of test/control samples; number of replicates; residue levels in the r.a.c.s to be used; representativeness of test commodities to the matrices of concern; etc.]

B. Test Procedures

1. Fortification ("spiking") procedure, if used [detail the manner in which the test compound(s) were introduced to the r.a.c.s];

2. A description of the processing procedure used and how closely it simulates commercial practice;

3. A description of the method(s) of residue analysis; 6/

4. A description of the means of validating the method(s) of residue analysis; 7/

4. A description of any storage stability validation studies that may have been done. 8/

IV. RESULTS/DISCUSSION

A. Residue Results [raw data; correction factor(s) applied, if any; recovery levels; storage stability levels, if applicable; direct comparison of residues in the r.a.c. with those in each processed product or processing fraction derived from that sample, etc.];

B. Statistical Treatment(s) [describe test(s) applied to the raw data];

C. Quality Control [if not covered elsewhere: control measures/precautions followed to ensure the fidelity of the processing study]; and

D. Other [any and all additional information the petitioner considers appropriate and relevant to provide a complete and thorough description of the processing study (studies).]

V. CONCLUSIONS

Discuss conclusions that may be drawn re the concentration/reduction of the test compound(s) in the test matrices as a function of the standard commercial processing procedure, and the need of food/feed food additive tolerances.

VI. CERTIFICATION

Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number, date).

VII. TABLES/FIGURES

A. Table(s) of raw data from the processing study; method recovery data; storage stability recovery data (if applicable); etc.; and

B. Graphs, Figures, Flowcharts, etc. (as relevant; include the processing procedure).

VIII. REFERENCES

IX. APPENDIX(ES)

A. Representative chromatograms, spectra, etc. (as applicable);

B. Reprints of methods and other studies [unless physically located elsewhere in the overall data submission, in which case cross-referencing will suffice] which will support the registrant's conclusions; and

C. Other [any relevant material not fitting in any of the other sections to this report.]

END NOTES

1/ Other aspects of the Magnitude of the Residue [see 40 CFR 158.125: crop field trials; meat/milk/poultry/eggs; fumigation uses; dermal uses; post-harvest treatments, etc.] will be addressed in separate Data Reporting Guideline documents.

2/ See Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, for a listing of the processed commodities and feed items derived from crops.

3/ For further details, see the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, §171-4(c)(2)(iv)(b) and the Tolerance Assessment System Issue Paper No. 4, "The Use of Post-Processing Residue Data to Estimate Residues in Foods 'As Eaten' and to Calculate Dietary Exposure to Pesticides."

4/ EPA Document #540/9-86-151. Available from the National Technical Information Service, Springfield, VA, as NTIS Document #PB86-248192.

5/ All of the data/information necessary to independently verify the results and conclusions drawn from the data results, etc., should be included.

Separate reports using the following guidance should be prepared for each study performed.

A processed food/feed study on a different r.a.c. will be considered relevant only if that r.a.c. is a related crop and if the experimental design is appropriate to current considerations.

6/ Refer to the Data Reporting Guideline on Analytical Methods for guidance in this area. Contained within EPA Document #540/9-86-151; from the National Technical Information Service, Springfield, VA, as NTIS Document #PB86-248192.

7/ Refer to the Data Reporting Guideline on Magnitude of the Residue: Crop Field Trials for guidance in this area. Contained within EPA Document #540/9-86-151; available from the National Technical Information Service, Springfield, VA, as NTIS Document #PB86-248192.

8/ Refer to the Data Reporting Guideline on Storage Stability testing for guidance in this area. Contained within EPA Document #540/9-86-151; available from the National Technical Information Service, Springfield, VA, as NTIS Document #PB-86-248192.